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AMENDMENT / RESPONSE TRANSMITTAL

Applicant : Weng, et al.
App. No : 10/633,726
Filed : August 4, 2003
For : CONTROLLED HIGH EFFICIENCY
LESION FORMATION USING HIGH
INTENSITY ULTRASOUND
Examiner : William C. Jung
Art Unit : 3768

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September 29, 2006

(Date)

Ryan E. Melnick, Reg. No. 58,621

Mail Stop Petition

Commissioner for Patents
P.O. Box 1450
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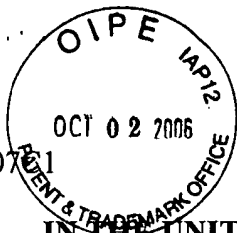
Sir:

Transmitted herewith for filing in the above-identified application are the following enclosures:

- (X) Petition To Withdraw Finality Under 35 C.F.R § 1.181(A)(3)
- (X) Appendix A in 2 pages.
- (X) Appendix B in 8 pages.
- (X) Return prepaid postcard.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

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Registration No. 58,621
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THERUS.00701

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Weng, et al.
Appl. No. : 10/633,726
Filed : August 4, 2003
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September 29, 2006

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Ryan E. Melnick

Ryan E. Melnick, Reg. No. 58,621

PETITION TO WITHDRAW FINALITY UNDER 35 C.F.R § 1.181(a)(3)

Mail Stop Petition

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The Applicants hereby petition the Director to exercise his supervisory authority under 35 C.F.R § 1.181(a)(3) to withdraw the finality of the Office Action mailed August 1, 2006. The Applicants submit that the issuance of a Final Office Action was premature. The pending claims are attached for the Director's convenience as Appendix A.

Statement of Facts

The Examiner issued a prior Final Office Action on December 15, 2005. After repeated failed attempts to reach the Examiner for a brief telephonic interview (several unreturned phone messages were left), the Applicants filed a Request for Continued Examination on June 13, 2006. In the submission with the Request for Continued Examination, the Applicants added new Claims 15-17. The new claims include several new limitations not present in any previously submitted claim. For example, Claim 15 includes the limitation of applying ultrasound to a uterine fibroid base from a plurality of angles. Claim 16 includes the limitation of heating tissue in a pie shaped region. No other claim currently pending or previously submitted contain these limitations.

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On August 1, 2006, the Examiner issued a Final Office Action as the first action after the RCE and the submission of new claims. In the Final Office Action, the Examiner indicated that the “arguments with respect to claims 15-17 have been considered but are moot in view of the ***new ground(s) of rejection.***” 8/1/06 Office Action, page 2, paragraph 2 (emphasis added). In the rejection of new Claims 15-17, the Examiner referred to a new portion of a reference previously of record and advanced the theory that the single reference rendered the new claims obvious. That portion of the reference had not been identified or discussed by the Examiner in any previous office action and the Examiner had never before applied an obviousness rejection based on the single reference.

After repeated failed attempts to reach the Examiner to discuss the finality of the office action (several unreturned phone messages were left), the Applicants have filed this petition.

Point to be Reviewed

Whether the issuance of a Final Office Action as the first action after an RCE is proper where the RCE included new claims containing new and distinct limitations not previously appearing in any other claim.

Discussion

M.P.E.P. § 706.07(b) provides that a final rejection is only proper on first action in a continuing application where all of the claims “(1) are drawn to the ***same invention*** claimed in the earlier application, and (2) would have been properly finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application.” (Emphasis added). The meaning of the phrase “same invention” is well understood in patent law. For example, “same invention” type double patenting under 35 U.S.C. § 101 has a long history of interpretation.

“Same invention” means identical subject matter. ... A reliable test ... is whether [one claim] could be literally infringed without literally infringing [a corresponding claim]. Is there an embodiment of the invention that falls within the scope of one claim, but not the other? If there is such an embodiment, then identical subject matter is not defined by both claims.

M.P.E.P. § 804(II)(A), citing *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1984); *In re Vogel*, 422 F.2d 438 (CCPA 1970); and *In re Ockert*, 245 F.2d 467 (CCPA 1957).

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Comparing new Claims 15-17 with Claims 10-14 (the remaining pending claims) in the instant application reveal that there are embodiments falling within the scope of Claims 10-14 that do not fall within the scope of Claims 15-17. For example, Claim 10 specifies to pre-select *one or more* tissue treatment site on the uterine fibroid. Thus, Claim 10 covers an embodiment where a single tissue treatment site is treated. Such an embodiment would not fall within the scope of Claims 15-17, which require repeated application of ultrasound around the circumference of the uterine fibroid from different angles (i.e., multiple tissue treatment sites). As another example, Claims 10-14 do not specify the geometry of the tissue treatment zones. Thus, these claims would cover the embodiment disclosed in the specification of a thin elongate column as a tissue treatment shape. See specification, page 10, lines 18-21 and Figure 2C. However, this embodiment would not fall within the scope of new Claim 16, which recites a pie shaped region. Therefore, Claims 10-14 could be literally infringed without infringing Claim 16. Accordingly, new Claims 15-17 cannot be said to be directed to the "same invention" as any of Claims 10-14.

In addition, the M.P.E.P. requires that the claims could be "properly ... rejected on the grounds ... of record." M.P.E.P. § 706.07(b). In this case, as explained in more detail in a response to the rejections of the new claims filed on the same date as this petition (attached as Appendix B), the rejection is not proper. It is based on a clear misinterpretation of a figure in the reference. If such improper rejections could serve as the basis for a first action final, then every first action after an RCE could be made final, simply by misapplying the art already of record to the new claims. Furthermore, the Examiner has admitted that the rejections of the new claims are based on "new ground(s)." 8/1/06 Office Action, page 2, paragraph 2. The Examiner rejected the new claims on the grounds that they were obvious over a single reference. No other claims have been or are currently rejected on the grounds that this single reference renders them obvious.

Action Requested

The Applicants respectfully request that the finality of the August 1, 2006 Office Action be withdrawn.

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No fee is believed due with this petition since no fee is referred to in 35 C.F.R. § 1.181(a)(3). *See* 37 C.F.R. § 1.181(d) (indicating that if a fee is required, "the appropriate section ... will so indicate"). However, if a fee is determined to be due, please charge any required fees, including any fees for extension of time, to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 9-29-06

By: Ryan E. Melnick
Ryan E. Melnick
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Appendix A

THERUS.007C1

Serial No.: 10/633,726

Filing Date: August 04, 2003



**CONTROLLED HIGH EFFICIENCY LESION FORMATION USING HIGH
INTENSITY ULTRASOUND**

CLAIMS as amended June 13, 2006

1-9. (CANCELLED).

10. (PREVIOUSLY PRESENTED) A method of ultrasonically cutting off the blood supply to a uterine fibroid, comprising the following steps of:

- a) providing an ultrasonic transducer configured to emit focused high intensity ultrasound energy;
- b) pre-selecting one or more tissue treatment sites located on the uterine fibroid whereby necrosing the tissues at the one or more tissue treatment site will decrease the blood supply to the uterine fibroid.

11. (PREVIOUSLY PRESENTED) An efficient heating method using high intensity ultrasound energy comprising the following steps:

- a) providing an ultrasound transducer configured to emit focused high intensity ultrasound energy;
- b) determining a tissue treatment zone; and
- c) energizing the ultrasound transducer to cause pre-focal heating and necrosis at the tissue treatment zone.

12. (PREVIOUSLY PRESENTED) The method of claim 11 wherein the pre-focal heating of the tissues causes temperature of the issue to increase to about 50°C.

13. (PREVIOUSLY PRESENTED) The method of claim 11, wherein the pre-focal heating of the tissue treatment zone improves efficiency of the overall treatment.

14. (PREVIOUSLY PRESENTED) The method of claim 11, wherein the tissue treatment zone is determined such that necrosis at the tissue treatment zone causes a decrease in blood supply to a tumor.

15. (NEW) A method of treating a uterine fibroid, comprising:

applying high intensity focused ultrasound energy selectively to the uterine fibroid base; and

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Filing Date: August 4, 2003

repeating the application of high intensity focused ultrasound to the uterine fibroid base from a plurality of angles around the circumference of the uterine fibroid.

16. (NEW) The method of claim 15, wherein each application of high intensity focused ultrasound causes heating of tissue in a pie shaped region.

17. (NEW) The method of claim 15, wherein the repeated applications cause substantially the entire uterine fibroid base to be heated.

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Appendix B

THERUS.007C1



COPY

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Weng, et al.
Appl. No. : 10/633,726
Filed : August 4, 2003
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EFFICIENCY LESION
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INTENSITY ULTRASOUND
Examiner : William C. Jung
Group Art Unit : 3768

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September 29, 2006

(Date)

Ryan E. Melnick

Ryan E. Melnick, Reg. No. 58,621

AMENDMENT AFTER FINAL

Mail Stop AF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Final Office Action mailed August 1, 2006, please find the enclosed amendments and remarks.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 4 of this paper.

AMENDMENTS TO THE CLAIMS

- 1-9. (CANCELLED).
10. (PREVIOUSLY PRESENTED) A method of ultrasonically cutting off the blood supply to a uterine fibroid, comprising the following steps of:
- a) providing an ultrasonic transducer configured to emit focused high intensity ultrasound energy;
 - b) pre-selecting one or more tissue treatment sites located on the uterine fibroid whereby necrosing the tissues at the one or more tissue treatment site will decrease the blood supply to the uterine fibroid.
11. (CURRENTLY AMENDED) An efficient heating method using high intensity ultrasound energy comprising the following steps:
- a) providing an ultrasound transducer configured to emit focused high intensity ultrasound energy;
 - b) determining a tissue treatment zone; and
 - c) energizing the ultrasound transducer to cause pre-focal heating and necrosis of a substantial portion of tissue between the transducer and the transducer's focal point at the tissue treatment zone.
12. (PREVIOUSLY PRESENTED) The method of claim 11 wherein the pre-focal heating of the tissues causes temperature of the issue to increase to about 50°C.
13. (PREVIOUSLY PRESENTED) The method of claim 11, wherein the pre-focal heating of the tissue treatment zone improves efficiency of the overall treatment.
14. (PREVIOUSLY PRESENTED) The method of claim 11, wherein the tissue treatment zone is determined such that necrosis at the tissue treatment zone causes a decrease in blood supply to a tumor.
15. (PREVIOUSLY PRESENTED) A method of treating a uterine fibroid, comprising:
- applying high intensity focused ultrasound energy selectively to the uterine fibroid base; and
 - repeating the application of high intensity focused ultrasound to the uterine fibroid base from a plurality of angles around the circumference of the uterine fibroid.

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16. (PREVIOUSLY PRESENTED) The method of claim 15, wherein each application of high intensity focused ultrasound causes heating of tissue in a pie shaped region.

17. (PREVIOUSLY PRESENTED) The method of claim 15, wherein the repeated applications cause substantially the entire uterine fibroid base to be heated.

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REMARKS

Claim 11 has been amended to clarify that a substantial portion of the tissue between the transducer and the transducer's focal point is necrosed. Support for this amendment may be found in the specification, for example, on page 7, lines 4-20; page 10, lines 5-35; and Figures 2A-2D. Claims 10-17 remain pending in the application. The Applicant's have carefully considered all of the Examiner's rejection but respectfully submit that the claims are allowable for at least the following reasons.

Finality of Office Action

The Applicants respectfully submit that the finality of the present Office Action is premature and request that the Examiner withdraw the final status of the action. The present Office Action is the first office action after submission of an RCE on June 13, 2006, in which new Claims 15-17 were presented for the first time. A first office action in a continuing application may only be made final if all of the claims "(1) are drawn to the *same invention* claimed in the earlier application, and (2) would have been properly finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application." M.P.E.P. § 706.07(b) (emphasis added). For one claim to be the "same invention" as another claim, there must be no embodiment that falls within the scope of one but not the other. See M.P.E.P. § 804(II)(A), citing *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1984); *In re Vogel*, 422 F.2d 438 (CCPA 1970); and *In re Ockert*, 245 F.2d 467 (CCPA 1957). Such is not the case when comparing new Claims 15-17 with previously presented Claims 10-14.

For example, Claim 10 covers an embodiment where a single tissue treatment site is treated. Such an embodiment would not fall within the scope of Claims 15-17, which require repeated application of ultrasound around the circumference of the uterine fibroid from different angles (i.e., multiple tissue treatment sites). As another example, Claims 10-14 do not specify the geometry of the tissue treatment zones and thus cover embodiments having any geometry (e.g., the thin elongate column described on page 10, lines 18-21 and Figure 2C). However, this embodiment would not fall within the scope of new Claim 16, which recites a pie shaped region. Accordingly, new Claims 15-17 are not directed to the "same invention" as presented prior to submission of the RCE. Therefore, finality of the Office Action is inappropriate. Furthermore, as discussed in more detail below, the rejection of Claims 15-17 is improper and therefore the

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claims are not "properly ... rejected on the grounds ... of record." In addition, the Examiner has admitted in the Office Action that the rejections of Claims 15-17 are based on "new ground(s)" (i.e., not the grounds of record). For these additional reasons, finality of the Office Action is inappropriate.

The Applicants have submitted a petition to the Director to have the finality of the present Office Action withdrawn. For the Examiner's reference, a copy of the petition is attached as Appendix A. However, the Applicants request that the Examiner withdraw the finality of the Office Action, removing the need for the Director to act. *See* M.P.E.P. § 706.07(d). Should the Examiner withdraw the finality of the Office Action and enter the enclosed amendments but not issue Notice of Allowance, the Applicants request that the Examiner delay further action until a telephonic interview can be conducted. An interview request is being filed herewith.

Rejection under § 102

The Examiner maintained rejection of Claim 10 under 35 U.S.C. § 102(e) as being anticipated by Vaezy et al. (U.S. Patent No. 6,425,867). The Examiner refers to column 6, lines 42-45 of Vaezy et al., which refers to cauterization of tissue to prevent or arrest "bleeding." However, arresting "bleeding" is not the same thing as decreasing blood supply to a fibroid. In fact, Vaezy et al. indicates that arresting bleeding is an alternative embodiment to treating a uterine fibroid. In column 6, lines 1-6, Vaezy et al. refers to the various therapeutic effects that can be achieved with its system. Treating a uterine fibroid (line 1) and treating an excessive bleeding condition (line 6) are referred to in the alternative. Similarly, arresting bleeding and causing tissue necrosis are referred to in the alternative in column 6, lines 44-45. Thus, the disclosure in Vaezy et al. regarding arresting bleeding has nothing to do with decreasing blood supply to a uterine fibroid. Rather, it refers to treating various bleeding conditions where a mammalian female has bleeding from her reproductive system.

This conclusion is consistent with the ordinary meaning of the word "bleeding," which refers to "the escape of blood from an injured vessel." *Dorland's Illustrated Medical Dictionary*, 29th ed. (2000), entry for "bleeding" (attached as Appendix B). In contrast, decreasing blood supply to a uterine fibroid involves reducing flow of blood *within* a blood vessel. Stopping blood flow from a ruptured vessel may in fact increase blood flow within the vessel, thus

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achieving the opposite effect as claimed in Claim 10. Accordingly, the Applicants respectfully submit that the disclosure in Vaezy et al. regarding "bleeding" does not anticipate Claim 10.

Rejections under § 103

The Examiner maintained rejections of Claims 11, 13, and 14 under 35 U.S.C. § 103(a) as being obvious over Vaezy et al. in view of Chapelon et al. (U.S. Patent No. 5,601,526) and Claim 12 as being obvious over Vaezy et al. in view of Chapelon et al. in further view of Ribault et al. (U.S. Patent No. 6,488,639). The Examiner argued that although heating outside of the focal point is not specifically stated in the references, the region surrounding the focal point would be incidentally heated. The Applicants have amended Claim 11 to clarify that the pre-focal heating is sufficient to also cause necrosis of a substantial portion of the tissue in the pre-focal region. In contrast, the ultrasonic application described by Chapelon would not be sufficient to heat a substantial pre-focal region to temperatures sufficient to cause necrosis of tissue in that region. In fact, Chapelon discloses applying ultrasonic energy for only very short time periods. For example, thermal-effect ultrasound waves are applied for only "several microseconds up to several milliseconds" and cavitation ultrasound waves are applied from "about 0.5 microseconds" to "about 100 milliseconds." Chapelon et al., column 10, lines 25-28 and 52-55. Such duration of application would be insufficient to cause necrosis of a substantial portion of tissue between the transducer and the transducer's focal point. For example, one non-limiting embodiment disclosed in the instant specification involved a continuous treatment time of approximately two minutes. *See* specification, page 10, lines 12-17.

In addition, Chapelon et al. provides no motivation to increase treatment time at a single focal point since its disclosed method involves performing "point-by-point treatment, each of said points being determined by the said focal point or region F, in order to cover the whole volume of the target 16 to be treated." Chapelon et al., column 8, lines 50-54. It is precisely this point-by-point treatment method, and the long total treatment time that it entails, that the Applicants have overcome by their method. *See* specification, page 3, lines 18-37 (describing prior methods and noting that "[t]he therapeutic ultrasound beam is focused inside tissue to a small spot of a few millimeters in size. At the focus, tissue temperature rapidly exceeds a level sufficient to cause tissue necrosis, thus achieving the desired therapeutic effect. Outside of the focus, ultrasound energy is less concentrated, tissue temperature rise remains below the necrosis

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level during the typically short exposure times employed. To treat a tissue volume larger than the focal spot, in the prior art, the ultrasound focus is deflected mechanically or electronically to scan, or incrementally expose, the target tissue volume. One disadvantage of the current high intensity ultrasound therapy is its inefficiency when treating large tumors or heating a large volume of tissue.”). Accordingly, the Applicants respectfully submit that Chapelon et al., alone or in combination with the other cited art, does not teach or suggest all of the limitations in Claims 11-14.

The Examiner also rejected new Claims 15-17 under 35 U.S.C. § 103(a) as being obvious over Vaezy et al. The Examiner admitted that Vaezy et al. does not disclose HIFU being applied in angles around the circumference of the uterine fibroid, but argues that such a method is obvious over Figure 11. The Examiner states that Figure 11 depicts HIFU transmission being emitted in a beam having circular path such that the uterine fibroid would be covered in angles around the circumference. In fact, as is clearly stated by Vaezy et al., Figure 11 depicts a semicircular shaped “ultrasound image 142” created by an imaging transducer array. Vaezy et al., column 21, lines 23-31. The HIFU transmission is in fact only applied to the focused “treatment site 144.” *Id.* Thus, Figure 11 only demonstrates that an acquired ultrasound image can include the treatment site where the HIFU transmission is focused. Neither Figure 11, nor the discussion regarding it, teach anything regarding repeated transmission of HIFU from various angles nor treating around the circumference of the base of a uterine fibroid. Accordingly, the Applicants respectfully submit that Vaezy et al. does not teach or suggest all of the limitations in Claims 15-17.

CONCLUSION

The Applicants submit that by the foregoing amendments and remarks, they have overcome all of the Examiner’s rejections and request a timely issuance of a Notice of Allowance. In the event that the Examiner does not issue such a Notice, the Applicants respectfully request withdrawal of the premature finality of the Office Action and the granting of a telephonic interview. In the event that the Examiner does not issue a Notice of Allowance or withdraw the finality of the Office Action, the Applicants respectfully submit that entry of the amendments are nonetheless appropriate since they of such a simple nature that they only require

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a cursory review by the Examiner and present the claims in better form for consideration on appeal. See M.P.E.P. §§ 714.12 and 714.13.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

COPY

Dated: 9-29-06

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